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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,709	09/18/2000	Hiroyuki Fujita	001200	4404

7590 11/20/2001

Armstrong Westerman Hattori McLeland & Naughton  
1725 K Street NW  
Suite 1000  
Washington, DC 20006

EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 11/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/663,709	FUJITA, HIROYUKI
Examiner	Art Unit	
Anish Gupta	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 1-10 is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6-8</u> .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the claim states that the "polypeptide ingredient having a molecular weight of at least 5000 is at most 10% by weight." However it is unclear what the "at most 10% by weight" is referring to. Is this a reference to concentration of the polypeptide in the composition or is a modification of the molecular weight. Clarification is requested.

In claim 5 and 6, the claim states that the "fish meat is a residue from extraction of the dried fish with boiled water." However it is unclear what part of the fish meat constitute "a residue." Clarification is requested.

Applicants are requested to delete the numbers in the left margin of the page since this numbering can become confusing with the numbering of the claims.

For the claimed peptides, Applicants are requested to place the appropriate SEQ ID NO. next to the corresponding peptide. Applicants are also requested to amend the specification in this manner as well.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Masayasu.

The claims are drawn to a angiotensin converting enzyme inhibitor.

The reference teach an angiotensin enzyme inhibitor that has the sequence IVGRPRHQG (see abstract). Note that this peptide is same peptide claimed in claim 2, line 16, of the instant application. The reference further states that the peptide is obtained by hydrolysis of actin at 10-85oC for .1-48hr (see abstract). Although the reference does not teach the method of isolating the peptide as claimed, the claims are drawn to a product. The MPEP states that “[t]he patentability of a product does not depend on its method of production. If the product in the product by process claim is the same as or obvious from the product of the prior art, the claims is unpatentable even though the prior product was made by a different process.” MPEP 2113.

4. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshikawa et al. (US 5,369,015)

The claims are drawn to a angiotensin converting enzyme inhibitor.

The reference teach an angiotensin enzyme inhibitor that has the sequence Ile-Lys-Trp (see col. 2, lines 49-54). Note that this peptide is same peptide claimed in claim 2, line 8, of the instant application. The reference teaches that the peptides are obtained from dried bonito by subjecting to hot water, and hydrolyzed using a thermolysin or pepsin (see col. 3, lines 44-52).

5. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al.

The claims are drawn to a angiotensin converting enzyme inhibitor.

The reference teach an angiotensin enzyme inhibitor that has the sequences of IY, IWHHR, IVGRPRHQG, IKPLNY, ALPHA, FQP, LKPNM, DYGLYP (see page 1543). Note that this peptide is same peptide claimed in claim 2, line 4-5, 11-16, of the instant application. The reference teaches that the peptides are obtained from dried bonito by subjecting to hot water, and hydrolyzed using a thermolysin or pepsin (see page 1542).

6. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Suetsuna.

The claims are drawn to a angiotensin converting enzyme inhibitor.

The reference teach an angiotensin enzyme inhibitor that has the sequence Leu-Lys-Tyr-Pro-Ile-Glu (see abstract). Note that this peptide comprises the same peptide claimed in claim 2, line 9, of the instant application. The

reference further states that the peptide is obtained by hydrolysis of sardine muscle (see abstract). Although the reference does not teach the method of isolating the peptide as claimed, the claims are drawn to a product. The MPEP states that “[t]he patentability of a product does not depend on its method of production. If the product in the product by process claim is the same as or obvious from the product of the prior art, the claims is unpatentable even though the prior product was made by a different process.” MPEP 2113.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Anish Gupta*  
Anish Gupta

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600